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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,622	12/31/2003	Sue K. DeNise	MMI1150	2415

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EXAMINER	
THOMAS, DAVID C	
ART UNIT	**PAPER NUMBER**
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,622	DENISE ET AL.	
	Examiner	Art Unit	
	David C. Thomas	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *1-27 and 43-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-42 and 52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/27/2006* ~~*1445/2004*~~ *10-28-04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 28-42 and 52-55 in the reply filed on January 8, 2007 is acknowledged. Claims 1-27 and 43-51 are withdrawn from further prosecution. In the case of the restriction of invention groups, the traversal is on the grounds that there is no burden searching both groups. This is not found persuasive for several reasons. First, the separate classification of the two groups is prima facie evidence of burden, which evidence has not been rebutted. Second, the search for the product claims (isolated polynucleotides and vectors or cells comprising the polynucleotides, oligonucleotides and primers that bind to the polynucleotides, and kits comprising the oligonucleotides and primers) is an entirely distinct search from the method claims, since the prior art which may be used to reject product claims are often entirely unrelated references which share common products.

In the case of the restriction of nucleotide sequences, new policy was recently instituted at the USPTO to restrict searches to one sequence per group (see Official Gazette article of February 22, 2007 that rescinds the partial waiver of restriction practice for sequences that allowed up to ten sequences per application in the 1996 ruling). For examination purposes, only one sequence will be searched in each group since this places an undue burden on the Examiner and Office resources since a search in multiple expansive databases is required for every sequence. Since only one sequence among the group of SEQ ID NOs. 1-4868 and 64887-64895 and one sequence among the group of SEQ ID NOs. 4869-19472 and 64896-64922 is required

to perform the invention according to claims 28 and 32, the election of SEQ ID NOS. 4518 and 5719 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. Neither Table 5 nor Table 6 appears in the written version or disc version of the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 36 refers to primers listed in Table 6, but no such Table is found in the Specification (printed or disc versions). Therefore, claim 36 cannot be interpreted.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (GenBank Accession No. AQ112913 (1998).

Adams teaches an isolated polynucleotide comprising at least 50 contiguous nucleotides of SEQ ID NOS: 4518, wherein the polynucleotide is less than or equal to about 500,000 nucleotides in length (GenBank Accession No. AQ112913 (1998) is a 476-bp polynucleotide with complete homology of nucleotides 174-248 to nucleotides 18-92 of SEQ ID No. 4518).

7. Claims 32-35 and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by New England Biolabs Catalog, Random Primer 24 (New England Biolabs, Product #1256, page 121 (1998-1999 catalog)).

With regard to claims 32-34, New England Biolabs teaches an isolated oligonucleotide that binds to SEQ ID NOS: 4518 or is identical to SEQ ID NOS: 5719, wherein the oligonucleotide is at least 10 or at least 15 nucleotides in length (New England Biolabs Catalog teaches a primer, Random Primer 24, which contains approximately 10 copies per 1.0 A_{260} unit vial of every possible primer sequence, and therefore would inherently contain primers which recognize at least a 10-base or 15-base sequence within SEQ ID NO. 4518, see calculation below).

Calculation of number of each 24-mer in a 1.0 A_{260} unit vial of NEB product #1256 (Random Primer 24):

Molecular weight of 24-mer:
24 × 325 daltons/nucleotide = 7,800 daltons = 7,800 g/mol

Number of possible 24-mers:

$4^{24} = 2.8 \times 10^{14}$ molecules

How many molecules of 24-mer in a vial sold by NEB:
1 A_{260} unit = 33 μg = 3.3×10^{-5} g
3.3×10^{-5} g ÷ 7,800 g/mol = 4.2×10^{-9} mol
$(4.2 \times 10^{-9}$ mol) × $(6.02 \times 10^{23}$ molecules/mol) = 2.5×10^{15} molecules

How many vials needed to sum to 1 of each possible 24-mer:
2.8×10^{14} molecules ÷ 2.5×10^{15} molecules = 0.11 vial

With regard to claim 35, New England Biolabs teaches a primer pair that binds to a first target region and a second target region of SEQ ID No. 4518 wherein a first primer of the primer pair and a second primer of the primer pair are at least 10 nucleotides in length and bind opposite strands of the target region, and prime polynucleotide synthesis from the target region in opposite directions across position 300 of SEQ ID No. 4518 (New England Biolabs Catalog teaches a primer, Random Primer 24, which contains approximately 10 copies per 1.0 A_{260} unit vial of every possible primer sequence, and therefore would inherently contain primers which are at least 10 nucleotides in length and would bind to sites on opposite strands flanking position 300 of SEQ ID NO. 4518, p. 121, also see calculation above).

With regard to claims 37-40, New England Biolabs teaches an isolated oligonucleotide that binds to SEQ ID NOS: 4518 or is identical to SEQ ID NOS: 5719, wherein the oligonucleotide is at least 10 or at least 15 nucleotides in length and wherein the terminal nucleotide binds to position 299, 300 or 301 of SEQ ID NOS: 4518 (New England Biolabs Catalog teaches a primer, Random Primer 24, which contains approximately 10 copies per 1.0 A_{260} unit vial of every possible primer sequence, and therefore would inherently contain primers which recognize at least a 10-base or 15-

base sequence within SEQ ID NO. 4518 and wherein the terminal nucleotide would bind to position 300 of SEQ ID NOS: 4518, p. 121, also see calculation above).

With regard to claims 52-55, New England Biolabs teaches a kit comprising an oligonucleotide probe, primer or primer pair, or combinations thereof, for identifying the nucleotide occurrence of at least one bovine single nucleotide polymorphism (SNP) corresponding to position 300 of SEQ ID NOS: 4518, wherein the SNP is associated with breed (New England Biolabs Catalog teaches a primer, Random Primer 24, which contains approximately 10 copies per 1.0 A_{260} unit vial of every possible primer sequence, and therefore would inherently contain one or more oligonucleotide probes, primers or primer pairs which recognizes sequences within SEQ ID NO. 4518 and wherein the terminal nucleotide would bind to position 300 of SEQ ID NOS: 4518 to allow detection of one or more SNPs or determination of a haplotype allele; probes can used for labeling DNA to a high specific activity, p. 121, also see calculation above).

8. Claims 32, 35, 37, 39, 52, 54 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al. (U.S. Patent Pub. No. 2001/0053519).

With regard to claim 32, Fodor teaches an isolated oligonucleotide that binds to SEQ ID NOS: 4518, wherein the oligonucleotide is at least 10 nucleotides in length (10-mer array contains all possible 10-mers that can be used for variety of purposes including use as a probe, primer for PCR, or a ligand, and therefore would inherently contain oligonucleotides which recognize at least a 10-base sequence within SEQ ID NO. 4518, paragraph 3, lines 21 and paragraph 122, lines 1-15).

With regard to claim 35, Fodor teaches a primer pair that binds to a first target region and a second target region of SEQ ID No. 4518 wherein a first primer of the primer pair and a second primer of the primer pair are at least 10 nucleotides in length and bind opposite strands of the target region, and prime polynucleotide synthesis from the target region in opposite directions across position 300 of SEQ ID No. 4518 (10-mer array contains all possible 10-mers that can be used for variety of purposes including use as a probe, primer for PCR, or a ligand, and therefore would inherently contain primers which would prime synthesis from the target region in opposite directions across position 300 of SEQ ID NO. 4518, paragraph 3, lines 21 and paragraph 122, lines 1-15).

With regard to claims 37 and 39, Fodor teaches an isolated oligonucleotide that binds to SEQ ID NOS: 4518, wherein the oligonucleotide is at least 10 nucleotides in length and wherein the terminal nucleotide binds to position 299, 300 or 301 of SEQ ID NOS: 4518 (10-mer array contains all possible 10-mers that can be used for variety of purposes including use as a probe, primer for PCR, or a ligand, and therefore would inherently contain oligonucleotides which would bind to SEQ ID NOS: 4518 and wherein a terminal nucleotide of the isolated oligonucleotide would bind to positions 299, 300 or 301 of SEQ ID NO. 4518, paragraph 3, lines 21 and paragraph 122, lines 1-15).

With regard to claims 52, 54 and 55, Fodor teaches a kit comprising an oligonucleotide probe, primer or primer pair, or combinations thereof, for identifying the nucleotide occurrence of at least one bovine single nucleotide polymorphism (SNP) corresponding to position 300 of SEQ ID NOS: 4518, wherein the SNP is associated

with breed (10-mer array contains all possible 10-mers that can be used for variety of purposes including use as a probe, primer for PCR, or a ligand, and therefore would inherently contain oligonucleotides which would bind to SEQ ID NOS: 4518 and wherein a terminal nucleotide of the isolated oligonucleotide would bind to position 300 of SEQ ID NO. 4518 and wherein the terminal nucleotide would bind to position 300 of SEQ ID NOS: 4518 to allow detection of one or more SNPs or determination of a haplotype allele, paragraph 3, lines 21 and paragraph 122, lines 1-15).

9. Claim 28 is rejected under 35 U.S.C. 102(e) as being anticipated by Wang (U.S. Patent Pub. No. 2004/0181048).

With regard to claim 28, Wang teaches an isolated polynucleotide comprising at least 50 contiguous nucleotides of SEQ ID NOS: 4518, wherein the polynucleotide is less than or equal to about 500,000 nucleotides in length (SEQ ID No. 3032 of Wang is a 1946-bp polynucleotide with complete homology of nucleotides 1347-1264 to nucleotides 10-92 of SEQ ID No. 4518).

With regard to claims 41 and 42, Wang teaches an isolated vector and cell comprising a polynucleotide comprising at least 50 contiguous nucleotides of SEQ ID NOS: 4518, wherein the polynucleotide is less than or equal to about 500,000 nucleotides in length (SEQ ID No. 3032 of Wang is a 1946-bp polynucleotide with complete homology of nucleotides 1347-1264 to nucleotides 10-92 of SEQ ID No. 4518; clones containing SEQ ID No. 3032 were prepared from genomic DNA by digestion with restriction enzymes, ligating fragments into phosphatased vector cut with same enzyme, and transformed into E. coli to prepare a library, which was screened by isolating

colonies and DNA sequencing of the inserts, paragraph 34, lines 1-20 and paragraph 35, lines 1-13).

10. Claims 32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang (U.S. Patent Pub. No. 2006/0057564).

Wang teaches an isolated oligonucleotide that binds to SEQ ID No. 4518 wherein the oligonucleotide is at least 10 or at least 15 nucleotides in length (SEQ ID No. 606487 of Wang is a 977-bp oligonucleotide with complete homology of nucleotides 171-188 to nucleotides 1-18 of SEQ ID No. 4518).

Allowable Subject Matter

11. Claims 29-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No prior art was found that teaches an isolated polynucleotide wherein the polynucleotide comprises 100 contiguous nucleotides of SEQ ID No. 4518 or comprises SEQ ID No. 4518 or wherein the polynucleotide further comprises a detectable label at a position corresponding to position 300 of SEQ ID No. 4518.

Conclusion

12. Claims 28, 32-42 and 52-55 are rejected. Claims 29-31 are objected to but would be allowable if rewritten, as discussed above.

Correspondence

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-

3320 and whose fax number is 571-273-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David C. Thomas 3/30/07

David C. Thomas
Patent Examiner
Art Unit 1637

JEFFREY FREDMAN
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3/30/07